UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,081	03/29/2007	Qiwang Xu	33888-400200	1679

27717 7590 08/30/2007

SEYFARTH SHAW LLP
131 S. DEARBORN ST., SUITE2400
CHICAGO, IL 60603-5803

EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	**PAPER NUMBER**
1623	
MAIL DATE	**DELIVERY MODE**
08/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,081	XU ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating psoriasis, systemic lupus erythematosus and hyperthyroidism, does not reasonably provide enablement for treating or controlling any other autoimmune disease by administering N-acetyl-D-glucosamine to a patient, as instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims
(B) The amount of direction provided by the inventor
(C) The existence of working examples
(D) The level of predictability in the art
(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Instant claim 6 is drawn to a method for treating and controlling local lesions and systematic symptoms caused by autoimmune reactions comprising administering an effective amount of N-acetyl-D-glucosamine or a pharmaceutical acceptable salt thereof to a patient. The recitation, "systematic symptoms caused by autoimmune reactions", is broad and is seen to encompass several symptoms and conditions.

The amount of direction provided by the inventor

The specification (page 1, second paragraph) teaches that symptoms such as fever, headache, vertigo, delirium, nausea, emesis and general malaise caused by autoimmune reactions are treated by immune suppression therapy using hormones and supporting therapy.

The existence of working examples

The working examples set forth in the instant specification are drawn to treatment of lupus erythematosus and hyperthyroidism using the said active agent. One of ordinary skill in the art will not extrapolate this to the treatment of any symptom or condition of autoimmune

reaction since the examples provided are not representative of all of the symptoms/conditions encompassed by the instant claim.

The level of Predictability in the Art

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427.2d 833, 166 USPQ (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since on of skill in the art cannot fully visualize or recognize all of the symptoms/conditions of autoimmune reactions. Handbook of Disabilities, drawn to autoimmune disorders, the course of the disorders is unpredictable. They are difficult to diagnose because of different possible symptoms and individual symptoms can vary (page 1, fourth paragraph; page 3, see under common treatments). There are also several different disorders and associated symptoms. Thus, the teachings of the Handbook of Disabilities clearly support that the instantly claimed invention is highly unpredictable due to variability in the symptoms and difficulty in diagnosis.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the controlling and treating of all local lesions and systematic symptoms via administration of a single compound, N-acetyl-D-glucosamine. One of ordinary skill in the art would be required to perform undue experimentation to determine which, if any, of the myriad

conditions and symptoms would be treatable or controllable by administration of the said active agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 provide for the use of N-acetyl-D-glucosamine, but, since the claim does not set forth any steps involved in the method, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/550,784 ('784). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claims 1-5 are drawn to a use of N-acetyl-D-glucosamine or pharmaceutically acceptable salt thereof in treating and controlling local lesions and systematic symptoms caused by autoimmune reactions and the use of the of N-acetyl-D-glucosamine or pharmaceutically acceptable salt thereof in the manufacture of a medicament for treating and controlling local lesions and systematic symptoms caused by autoimmune reactions

Claims 1-3 and 7 of '784 are drawn to a use of N-acetyl-D-glucosamine or pharmaceutically acceptable salt thereof in treating and controlling local lesions and systematic symptoms caused by infections of virus or bacteria and the use of the of N-acetyl-D-glucosamine or pharmaceutically acceptable salt thereof in the manufacture of a medicament for treating and controlling local lesions and systematic symptoms caused by infections of virus or bacteria.

Instant claims 6-9 are drawn to a method of treating and controlling local lesions and systematic symptoms caused by autoimmune reactions.

Claims 4-6 of '784 are drawn to a method of treating and controlling local lesions and systematic symptoms caused by infections of virus or bacteria.

Claims 1-7 of '784 differ from the instant claims in that the instant claims are drawn to symptoms cause by autoimmune reactions. '784 defines systematic symptoms of viral and

bacterial infections as fever, headache, vertigo delirium, nausea, emesis and general malaise (page 1, seconds paragraph). The same definitions also hold good for the systematic symptoms in the instant specification (page 1, second paragraph). However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that N-acetyl-D-glucosamine could be could be successfully employed in the method of '742.

In determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). In the instant case, '784 teaches the method for controlling local lesions and the same systematic symptoms applicant claims. Although the claims of '784 recite the cause of the symptoms to be virus or bacterial infection, one of ordinary skill in the art would readily recognize that the method taught by '784 could be employed in the method of controlling local lesions and treatment of the same symptoms as recited in the instant claims. One of ordinary skill in the art is seen as one having a PhD. The use of known active agent in the treatment of the same type of symptoms and conditions taught in the prior art is not seen to render the instantly claimed method unobvious over the art. Once the general method and active agent have

been shown to be useful for treating symptoms caused by autoimmune reactions, the burden is on the applicant to present reason or authority for believing that the same symptoms caused by bacteria or virus cannot be treated by using the same active agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton et al (US 5,217,962).

Burton et al teach the oral administration of N-acetyl glucosamine for the treatment of psoriasis (a local lesion). The dosage is about 300mg to 10,000g per day (col. 2, lines 52 through col. 3, line 3; col. 8, lines 30-46). This teaching of Burton is seen to meet the limitations of instant claims 6-9.

Conclusion

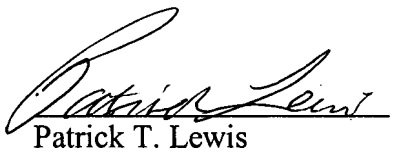
Claims 1-9 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK



Patrick T. Lewis
Primary Patent Examiner
Art Unit 1623